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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,268	03/04/2002	Robert Wyckoff	2001-8050-RA	4134
30184	7590	06/03/2005	EXAMINER	
MYERS & KAPLAN, INTELLECTUAL PROPERTY LAW, L.L.C. 1899 POWERS FERRY ROAD SUITE 310 ATLANTA, GA 30339			RAGONESE, ANDREA M	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/090,268	Applicant(s) WYCKOFF, ROBERT	
	Examiner Andrea M. Ragonese	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2005.
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
 4a) Of the above claim(s) 21-24 is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1-20 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☒ The drawing(s) filed on 02 March 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/02; 10/02; 11/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendment filed on March 2, 2005 has been entered. Examiner acknowledges that **claims 1** and **17** have been amended. Subsequently, **claims 1-20** are under consideration, while **claims 21-24** have been withdrawn from further consideration.

Response to Arguments

2. Applicant's arguments filed March 2, 2005 have been fully considered but they are not persuasive.

In response to applicant's argument (on pages 13-14) that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "wherein a generally negative pressure is created on the exterior surface of a user's neck, thereby effectively holding open the air pathways" and "by creating a negative pressure on the exterior surface of the neck, thereby drawing the neck out and holding air passages open") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In addition, recitations of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use—**such as "maintaining air pathway**

clearance” when the device is evacuated of all air present in the device—then it meets the claim limitation. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

Drawings

3. The drawings were received on March 2, 2005. These drawings are not accepted by the Examiner.

4. The drawings are objected to because of the following informalities:

- In Figures 5A and 5C, there is an element on the left-hand side of the drawing that does not have any corresponding reference characters to provide a description of its function.
- In Figures 5A and 5B, newly added elements **102a**, **102b** do not have a corresponding “snap” elements. Examiner believes elements **102a**, **102b** should be shown in same drawings.
- In Figures 5B and 5C, newly added elements **104a**, **104b** do not have a corresponding “magnetic” elements. Examiner believes elements **104a**, **104b** should be shown in same drawings.

5. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure

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number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. **Claims 1-5 and 10-11** are rejected under 35 U.S.C. 102(b) as being anticipated by Wirtz (US 4,657,003). Wirtz discloses device **82** for wear on the neck of a user which is fully capable of maintaining air pathway clearance (column 8, line 58 through column 9, line 37), as shown in Figures 12-14, when the air compartment defined between said support member **84** and the neck of the user is evacuated by valve **25**. The device **82** comprises:

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- a support member **84**, said support member **84** having an inner surface, an outer surface and a peripheral edge;
- securing means **88**, said securing means **88** carried by said support member **84** and said securing means **88** enabling retention of said support member on the neck of the user;
- retention means **89**, said retention means **89** enabling retention of said securing means **88** relative to said support member **84**;
- sealing means **94**, said sealing means **94** carried by said support member **84** proximate to said peripheral edge of said inner surface of said support member **84**—wherein “proximate” is defined by *Merriam-Webster Online Dictionary* as “very near, close”, thus meeting the claim limitation since sealing means **94** is “very near” or “close” to the peripheral edge of the inner surface of support member **84**—said sealing means **94** enabling substantially airtight positioning of said support member **84** against the neck of the user, said sealing means **94** generally protruding from said inner surface of said support member **84**, and said sealing means **94** defining an air compartment between said inner surface of said support member **84** and the neck of the user through an air compartment that is filled with or evacuated of air allowed in by valve **25** as described throughout prior art specification (see column 9, lines 17-20 for support regarding “evacuation”);
- at least one valve **25**, said valve **25** carried by said support member **84**, wherein said valve **25** enables the exit of air from said air compartment

between said inner surface of said support member and the neck of the user, just as provided for in other embodiments of the prior art invention and described throughout prior art specification.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. **Claims 6-9 and 16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wirtz (US 4,657,003), as applied to **claim 1** above, in view of Calabrese (US 4,886,052). Wirtz teaches an apparatus comprising all limitations recited in **claims 6-9 and 16**, but does not expressly disclose that the securing means includes both a strap and another attachment mechanism selected from the group consisting of a buckle, a snap, a clasp and a magnet or that the support member is formed of a plurality of linked segments. At the time of the invention was made, all of these types of attachment mechanisms for linking together more than one support member segment were very well known in the art and prevalently used. Specifically, Calabrese teaches that "a strap fastener...prevents further expansion of slit **35**, and firmly secures front collar half **12'** to the contour of the patient's neck" (column 9, lines 39-54). However, Calabrese also teaches that "[those] skilled in the art will clearly recognize that any suitable fastening means such as an adjustable buckle, snaps or the like, can be utilized to perform the function" (column 9, lines 54-57). Buckles, snaps, clasps and magnets are all

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equivalents in the field of securement. Therefore, it would have been obvious to one having ordinary skill in the art to use any one of these securement means as Applicant has done to firmly secure more than one support member segment together. Moreover, Applicant has not asserted that the specific securement means or the plurality of linked segments recited provides a particular advantage, solves a stated problem or serves a purpose different from that of a hook and loop fastener assembly attaching together two ends of a one-piece construction support member, thus the use of any other type of securement means or a multiple segmented support member lacks criticality in its utilization and design. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with any type of adjustable attachment mechanism that is capable of opening/sealing and closing/resealing a support member, whether it is constructed of one segment or more than one segment, around a patient's neck. Therefore, it would have been obvious to modify the apparatus of Wirtz by altering the securing means to be any one selected from the group of buckles, snaps, clasps and magnets and to secure more than one support member segment together because it is well known in the art to use these types of securing means in order to secure the multiple segments of a support apparatus to the neck of a patient.

10. **Claims 12, 17-18 and 20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wirtz (US 4,657,003), as applied to **claim 1** above, in view of Visness et al. (US 6,494,854 B1). Wirtz discloses an apparatus comprising all the limitations recited in **claims 12, 17-18 and 20**, with the exception of a gasket. However, the use of gasket was known at the time the invention was made. Specifically, Visness

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et al. teaches the use of gasket **100** “to disperse and cushion the weight of the device **30** as well as the resultant head and neck forces of the patient on the device **30**” (column 6, lines 12-38). In addition, gasket **100** defines a sealed region between the concave surface of the neck cuff and the neck of a user, which is an element of a gasket that is inherent in the use of a gasket. The Merriam-Webster Online Dictionary defines a gasket as “a material (as rubber) or a member (as an O-ring) used to make a joint fluid-tight.” Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Wirtz by adding a gasket underneath the support member because it is well known in the art, as taught by Visness et al., to use a gasket in order to make wearing the device more comfortable for the patient in addition to providing a sealed region around the neck.

11. **Claims 13-15** is rejected under 35 U.S.C. 103(a) as being unpatentable over Wirtz (US 4,657,003), as applied to **claim 1** above, in view of Sackner (US 4,452,252). Wirtz discloses an apparatus comprising all the limitations recited in **claims 13-15**, with the exception of a data collection port and means for measuring performance. However, the use of a data collection port and means for measuring performance was known at the time the invention was made. Specifically, Sackner teaches the use of device with a data collection port for analyzing “specific pulmonary events, such as snoring, coughing, apneas, swallows, etc.” (column 2, line 60 through column 3, line 9). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Wirtz by adding a measurement device with a data collection port because it is well known in the art, as taught by

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Sackner, to use such a device for monitoring a patient's vital signs in order to measure the performance of an apparatus.

12. **Claim 19** is rejected under 35 U.S.C. 103(a) as being unpatentable over Wirtz (US 4,657,003) in view of Visness et al. (US 6,494,854 B1), as applied to **claim 18** above, and further in view of Sackner (US 4,452,252). Wirtz discloses an apparatus comprising all the limitations recited in **claim 19**, with the exception of a data collection port. However, the use of a data collection port was known at the time the invention was made. Specifically, Sackner teaches the use of device with a data collection port for analyzing "specific pulmonary events, such as snoring, coughing, apneas, swallows, etc." (column 2, line 60 through column 3, line 9). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Wirtz by adding a measurement device with a data collection port because it is well known in the art, as taught by Sackner, to use such a device for monitoring a patient's vital signs in order to measure the performance of an apparatus.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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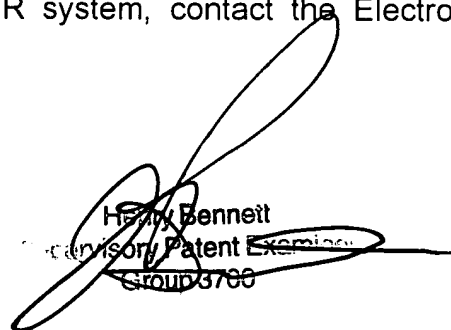
mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Andrea M. Ragonese whose telephone number is 571-272-4804**. The examiner can normally be reached on Monday through Friday from 9:00 am until 5:00 pm.

15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMR
May 31, 2005


Henry A. Bennett
Advisory Patent Examiner
Group 3700